DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 7, 2015

Spineway
% Rich Jansen, Pharm.D.
President
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K150036
Trade/Device Name: Blue Mountain Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 8, 2015
Received: April 9, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150036

Device Name
Blue Mountain Cervical Plate System

Indications for Use *(Describe)*
The Spineway Blue Mountain Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The Spineway Blue Mountain Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.
This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: January 8, 2015
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
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Trade Name: Blue Mountain Cervical Plate System
Product Class: Class II
Classification: 21 CFR 888.3060 Spinal intervertebral body fixation orthosis
Common Name: Spinal Fixation Device
Product Codes: KWQ
Panel Code: 87

Indications for Use:
The Spineway Blue Mountain Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The Spineway Blue Mountain Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.
This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.

Device Descriptions:
The Spineway Blue Mountain Cervical Plate System is a system that includes titanium alloy (per ASTM F136 and ISO 5832-3) plates and screws that are intended to stabilize the spine during the fusion process. The plates and screws are available in various sizes to accommodate patients' anatomy. The plates are contoured to follow the curves of the cervical spine.

Predicate Device(s):
The Spineway Blue Mountain Cervical Plate System is substantially equivalent to the Qualgenix Blue Mountain Cervical Plate System (K112809),

Technological Characteristics:
The Blue Mountain Cervical Plate System is very similar to the predicate device. The materials, screw type, screw diameters and screw locking mechanism is exactly the same as the predicate device. This submission includes new plate sizes and some new instruments.

Performance Data:
Risk analysis and validation activities were performed according to Spineway design control procedure. The risk analysis demonstrated that the subject addition to Blue Mountain Cervical Plate System is substantially equivalent to its predicate device. Spineway determined that the changes made to the device did not present a new worst case, and therefore, no new testing was conducted.

Conclusion:
Spineway concludes that the Spineway Blue Mountain Cervical Plate System is substantially equivalent to the predicates in regard to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.